

Cancer Clinical Trials Advisory Council

Meeting Minutes

December 13, 2011

Office of the Commissioner of Securities and Insurance (CSI) Conference Room, Helena and by phone

Council members present: **Kristin Page Nei**, American Cancer Society Cancer Action Network; **Marian Diaz**, Symetra Life Insurance Company; **Dr. Robert Geller**, Billings Clinic; **Ron Dewsnap**, Allegiance Benefit Plan Management; **Sharon DeJongh**, Bozeman Deaconess Cancer Center; **Paul Burns**, Cancer Patient; **Jo Duszkievicz**, Billings Clinic; **Cory Hartman**, New West Health Services; **Dr. Jack Hensold**, Bozeman Deaconess Cancer Center; **Brendan Steele**, Cancer Patient; **Diane Ruff**, Associated Employers Group Benefit Plan & Trust; **Russ Hill**, DOA-Health Care and Benefits Administration; **Dr. Ben Marchello**, Frontier Cancer Center and Montana Cancer Consortium; **Cori Cook**, EBMS; **Michael Foster**, Catholic Hospitals; **Rachel Peura for Monica Berner**, BCBS of MT; **Richard Miltenburger for Paul Bogumill**, Mountain West Benefits

Council members absent:

Dr. Grant Harrer, Benefis Health System; **Monica Berner**, BCBS of MT; **Paul Bogumill**, Mountain West Benefits

1. Welcome by Chair, adoption of minutes, review of agenda, and discussion on where we are headed.

Council chair Kristin Page Nei called the meeting to order at 1:05 PM and reviewed the agenda. She also reviewed the charges for the council as set forth by HB 615. After completing the definition of routine care, the council still needs to identify necessary federal policy changes to ERISA-regulated, self-funded plans and investigate what can be done at the state level. Kristin reminded the council of the influence they could have since they can make recommendations to Commissioner Lindeen who sits on the NAIC committee that will work on the rules for implementation of clinical trial coverage as charged by the ACA.

CSI staff recommended the council allow members to designate specific named alternates to represent their organizations at the meetings when they cannot attend. **Dr. Geller made a motion and Dr. Marchello seconded. The council voted to accept the motion unanimously.** Staff will contact Monica Berner and Paul Bogumill about alternate members for approval by the commissioner.

Dr. Hensold made a motion to adopt the minutes and Dr. Geller seconded the motion. The council voted unanimously to adopt the minutes from the October 28th meeting.

2. Dr. Marchello's presentation and discussion

Dr. Marchello was asked to educate the council on distinctions between the phases of trials and provide examples of trials. **He presented the [attached document](#)** emphasizing that the phases

of trials do not relate to cost or complexity. All kinds of treatments can be included in any of the phases. Phases are ordered in the sequence that a new treatment is studied.

Phase 2 and 3 trials are the most common in Montana. In phase 3 trials, the intervention drug would be covered by the drug company and the standard drug would need to be covered by the health plan. Phase 1 trials are usually for end stage patients who don't have any other options. Side effects are usually covered by the patient or payer. Medicare covers the costs of side effects at the 80% rate.

Council members provided some data on what phases of trials patients are participating in Montana. No cancer patients are on phase 1 through the Montana Cancer Consortium. Billings Clinic has put 33 patients on phase 1 trials in 3 years out of about 400 on cooperative group clinical trials. A tiny fraction of patients go on phase 1 trials in comparison to phases 2 and 3.

3. Continue defining "routine care" and working through ACA language

Kristin reminded the council that in the document they were working through the yellow highlighted text is what the council came to agreement on in the last meeting and the blue highlighted text is a new addition that was added from the EBMS proposal.

(a) COVERAGE

(1) IN GENERAL

The Council agreed to adopt all of section (1), including subsections (A), (B), and (C).

(2) ROUTINE PATIENT COSTS

The Council adopted this section at the last meeting with one addition.

(b) QUALIFIED INDIVIDUAL DEFINED

The Council adopted all this section at the last meeting with no changes.

(c) LIMITATIONS ON COVERAGE

The Council expressed confusion about the wording of this section, but seemed to agree it was standard language. Cori Cook offered to attempt a clarifying rewrite for the council.

(d) APPROVED CLINICAL TRIAL DEFINED—

(1) IN GENERAL—

A council member suggested adding language from the Medicare Final National Coverage Decision requiring "therapeutic intent," to specify that the trial must be more than experimental and investigational. Other members agreed that a patient in the trial must be diagnosed with a disease to receive coverage and the treatment should be intended to treat that disease. Healthy individuals who may be enrolled in a study group in a prevention trial would be covered by the trial sponsor. Ron Dewsnap made a motion that the council add item 2, "The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic

intent,” from the Medicare document to the council’s working document of definitions. Dr. Hensold seconded the motion. A member asked if “prevention” and “detection” were needed when we added “therapeutic intent.” Providers clarified that even a preventive or diagnostic trial has therapeutic intent. Council members agreed that “prevention” and “detection” should be kept.

Members then agreed to remove “other life threatening disease or conditions” as our charge is only about cancer clinical trials.

A vote was not taken on the motion as the council wished to see a draft of proposed changes.

Cori Cook offered to work the new additions to this section into a new draft she would prepare for the council to review before the next meeting. CSI staff offered to facilitate voting via email on a new draft once it is submitted.

(A) FEDERALLY FUNDED TRIALS

Ron Dewsnup made a motion to accept the entire section as it stands. Dr. Hensold seconded the motion. The council approved the motion unanimously.

Council members agreed that they needed more information on sections (B) and (C) before voting on them because oversight by the Food and Drug Administration does not include much regulation and this section applies to pharmaceutical trials. Marien Diaz, Dr. Marchello, and Dr. Hensold agreed to research more information on the section to bring it back to the council. CSI staff also offered to contact pharmaceutical representatives to find out more information on pharmaceutical company trials.

(2) CONDITIONS FOR DEPARTMENTS—

Ron Dewsnup made a motion to accept the section on the condition that the term “department” is clarified. Payers may not want to accept federally funded trials at face value without reviewing the trial’s peer review. CSI legal staff will clarify what “department” means and whether a state would need to include this language. One of the purposes of the language is to ensure the sponsor of the trial goes through these peer reviews and the language may provide that assurance.

Ron Dewsnup made the motion again to accept the section as it is, Dr. Marchello seconded it, and the council passed the motion unanimously.

Cori Cook made a motion that we eliminate items e) – h) as they are not relevant to our state efforts. Dr. Marchello seconded. It passed unanimously after brief discussion.

6. No public comment

7. Next meeting, next steps, assignments to members and staff

The group agreed to work via the list serve and plan toward a next meeting in mid-January. The week of January 16 was suggested. Teleconference is the preferred method.

Next steps-

- Cori Cook will submit a new draft of the council's adopted definitions of "routine care" including the new additions from the Medicare document and other re-wording.
- Marian Diaz, Dr. Marchello, Dr. Hensold, and CSI staff will research more information on pharmaceutical company sponsored trials for the council to consider.
- The council will hold discussion via the list serve on the above items.
- CSI staff will consolidate and categorize the "causes" statements that most council members agreed on into a new document.
- CSI staff will plan for a presentation on how to proceed with possible changes to ERISA-regulated, self-funded health plans.

Adjournment 3:30 PM